



08-12-05 10/530/139 PCT
JC06 Rec'd PCT/PTO 11 AUG 2005
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Jacek MARTYNOW et al.) Group Art Unit:
)
Serial No:	10/530,139) Examiner:
)
Filed:	April 4, 2005) Attorney Docket No: 9558/94047
) (Z-3215/05)
International Application No.	PCT/PL20/000099)
)
International Filing Date:	1 October 2003)
)
For:	Process and Intermediates to Prepare)
	17 β -hydroxy-7 α -methyl-19-nor-)
	17 α -pregn-5(10)en-20-yn-3-one)

INFORMATION DISCLOSURE STATEMENT

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The following documents relate to applicants' corresponding International Patent Application No. PCT/PL03/00099, filed October 1, 2003, International Publication No. WO 2004/031204 A2, published April 15, 2004, and are enclosed for the consideration of the U.S. Patent Examiner.

1. International PCT Patent Application No. PCT/PL03/00099, filed October 1, 2003, International Publication No. WO 2004/031204 A2, published April 15, 2004.
2. PCT International Search Report of March 17, 2004 and Notification of Transmittal thereof for PCT International Patent Application No. PCT/PL03/00099.
3. PCT Written Opinion of September 8, 2004, International Patent Application No. PCT/PL03/00099 for Process and Intermediates to Prepare 17 β -hydroxy-7 α -methyl-19-nor-17 α -pregn-5(10)en-20-yn-3-one.

4. PCT International Preliminary Examination Report of December 29, 2004 and Notification of Transmittal thereof, International Patent Application No. PCT/PL03/00099 for Process and Intermediates to Prepare 17 β -hydroxy-7 α -methyl-19-nor-17 α -pregn-5(10)-en-20-yn-3-one.

The patents, published applications and publications listed below were cited as references in the International Search Report of applicants' corresponding International PCT Patent Application No. PCT/PL03/00099, filed October 1, 2003, International Publication No. WO 2004/031204 A2, published April 15, 2004 or were located during a search for the subject matter of the invention. The patents and published patent applications listed below generally relate to subject matter of the invention, but do not fairly teach or suggest the claimed Process and Intermediates to Prepare 17 β -hydroxy-7 α -methyl-19-nor-17 α -pregn-5(10)-en-20-yn-3-one. Copies of the listed patents, published patent applications and publications below are enclosed for consideration by the Examiner.

1. Department of Organic Chemistry, Southwest Foundation for Research and Education; Dinunno, Cecil M. et al: "Methylnorethindrone 10 β : hydroperoxide: Isolation and Characterization"; *Steroids*; Volume 42, Number 4, October 1983, pp. 401-408.

2. Department of Chemistry, State University of New York; Robert M. Hoyte et al.; "7 α -Methyl-17 α -(E-2'-[¹²⁵I]iodovinyl)-19-nortestosterone: A new radioligand for the detection of androgen receptor." *Steroids*; Vol. 58, January 1993, pp. 13-23.

3. Blye et al. U.S. Patent No. 4,308,265, granted December 29, 1981, pertains to a 7 α -Methylnorethindrone Enanthate and Its Use in Long Term Suppression of Fertility in Female Mammals.

4. Organon, Scientific Development Group, N.P. van Vliet et al.; "An alternative synthesis of 17 β -hydroxy-7 α -methyl-19-nor-17 α -pregn-5(10)-en-20-yn-3-one" (Org OD 14); *Recl. Trav. Chim. Pays-Bas* 105, 111-115 (1986).

5. International Publication No. PCT/EP99/07768, filed October 11, 1999, International Publication No. WO 00/23460, published April 27, 2000, of AKZO NOBEL N.V. for High Purity Composition Comprising (7 α ,17 α)-17 hydroxy-7methyl-19nor-17-Pregn-5(10)-en-20-yn3-one.

6. Bucourt U.S. Patent No. 3,534,139, granted October 13, 1970, pertains to 17 α -Ethynyl-8 α -H- $\Delta^{5(10)}$ -Estrene-17 β -OL-3-One, Process of Preparation, Therapeutic Administration and Intermediates.

7. Hofmeister et al. U.S. Patent No. 4,945,064, granted July 31, 1990, pertains to Estrane and Androstane Derivatives, Process for Producing Them and Preparations Containing These Compounds.

8. Ringold et al U.S. Patent No. 2,806,030, granted September 10, 1957, pertains to Cyclopentanophenanthrene Derivatives and Process for the Preparation Thereof.

9. Anner et al. U.S. Patent No. 3,318,928, granted May 9, 1967, pertains to 7 α -Alkyl-17 α -Alkynyl-Estradiols.

10. Edwards U.S. Patent No. 3,904,611, granted September 9, 1975, pertains to Preparation of 17 α -Propadienyl Steroids.

11. Grunwell et al. U.S. Patent No. 3,928,398, granted December 23, 1975, pertains to Derivatives of 7 α -Methylestr-4-EN-3 α -17 β -Diol.

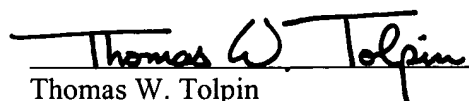
12. Blye et al. U.S. Patent No. 4,252,800, granted February 24, 1981, pertains to 7 α -Methylnorethindrone Enanthate and its Use in Long Term Suppression of Fertility in Female Mammals.

13. Nique et al. U.S. Patent No. 4,874,754, granted October 17, 1989, pertains to Novel 19-Nor-Steroids.

14. Solomon et al. U.S. Patent No. 3,475,465, granted October 28, 1969, pertains to Process for the Preparation of $\Delta^{5(10)}$ -3-Keto-19-Nor-Steroids.

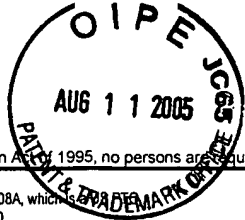
Authorization is hereby given to charge any fees in connection with this Information Disclosure Statement and this U.S. Patent Application to our Deposit Account No. 23-0920.

Respectfully submitted,


Thomas W. Tolpin
Registration Number 27,600
Attorney for Applicants

Dated: August 11, 2005

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Substitute for form 1449A/PTO and 1449B/PTO**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/530,139
Filing Date	April 4, 2005
First Named Inventor	Jacek MARTYNOW et al.
Art Unit	
Examiner Name	
Attorney Docket Number	9558/94047 (Z-3215/05)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US-4,308,265	12-29-1981	Blye et al.	
		US-3,534,139	10-13-1970	Bucourt	
		US-4,945,064	07-13-1970	Hofmeister et al.	
		US-2,806,030	09-10-1957	Ringold et al.	
		US-3,318,928	05-09-1967	Anner et al.	
		US-3,904,611	09-09-1975	Edwards	
		US-3,928,398	12-23-1975	Grunwell et al.	
		US-4,252,800	02-24-1981	Blye et al.	
		US-4,874,754	10-17-1989	Nique et al.	
		US-3,475,465	10-28-1969	Solomon et al.	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		PCT/PL03/00099 WO 2004/031204 A2	10-01-2003 04-15-2004	Przedsiębiorstwo Farmaceutyczne Anpharm S.A.		
		PCT/EP99/07768 WO 00/23460	10-11-99 04-27-2000	Akzo Nobel N.V.		

Examiner
SignatureDate
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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10/24/2001 W&K Substitute for Form PTO-SB/08A, which is a US PTO Substitute for form 1449A/PTO and 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/530,139
		Filing Date	April 4, 2005
		First Named Inventor	Jacek MARTYNOW et al.
		Art Unit	
		Examiner Name	
Sheet 2 of 2	Attorney Docket Number	9558/94047 (Z-3215/05)	

OTHER ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		Department of Organic Chemistry, Southwest Foundation for Research and Education; Dinunno, Cecil M. et al: "Methylnorethindrone 10.β: hydroperoxide: Isolation and Characterization"; <i>Steroids</i> ; Volume 42, Number 4, October 1983, pp. 401-408.	
		Department of Chemistry, State University of New York; Robert M. Hoyte et al.; "7α-Methyl-17α-(E-2'-[¹²⁵ I]iodovinyl)-19-nortestosterone: A new radioligand for the detection of androgen receptor;" <i>Steroids</i> ; Vol. 58, January 1993, pp. 13-23.	
		Organon, Scientific Development Group, N.P. van Vliet et al.; "An alternative synthesis of 17β-hydroxy-7α-methyl-19-nor-17α-pregn-5(10)-en-20-yn-3-one" (Org OD 14); <i>Recl. Trav. Chim. Pays-Bas</i> 105, 111-115 (1986).	
		PCT International Search Report of March 17, 2004 and Notification of Transmittal thereof for PCT International Patent Application No. PCT/PL03/00099.	
		PCT Written Opinion of September 8, 2004, International Patent Application No. PCT/PL03/00099 for Process and Intermediates to Prepare 17β-hydroxy-7α-methyl-19-nor-17α-pregn-5(10)en-20-yn-3-one.	
		PCT International Preliminary Examination Report of December 29, 2004 and Notification of Transmittal thereof, International Patent Application No. PCT/PL03/00099 for Process and Intermediates to Prepare 17β-hydroxy-7α-methyl-19-nor-17α-pregn-5(10)en-20-yn-3-one.	

Examiner Signature	Date Considered
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¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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9558-94047



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Date of Deposit: August 11, 2005

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